UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,110	04/12/2001	Pankaj J. Pasricha	265.0009 0101	5306

26813 7590 08/12/2003

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	18

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Advisory Action	Application No.	Applicant(s)	
	09/834,110	PASRICHA ET AL.	
	Examiner	Art Unit	
	Joseph T Woitach	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____ Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *18-43*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Continuation of 2 NOTE: The amendment to the specification to specifically recite substance P has to be considered with respect to new matter. Additionally, the amendments to the claims encompassing "suffering from a gatrointestinal disorder" and "suffering from an enter nervous disorder" would have to be specifically searched and considered. Further, the support for "alimentary tract" must be considered under 112, first and second paragraph, in particular with respect to treating any specific degenerative disorders. Finally, the recitaiton of 'isolated' stem cell requires a new search and consideration for obtaining such a cell from any organism and using said cell in the contex of the claimed methods.

Continuation of 5 does NOT place the application in condition for allowance because: Applicants' arguments have been fully considered but not found persuasive. Specifically, it is acknowledged that immunosuppressants can be administered after transplantation, however there is no suppressive therapy for avoiding the reaction to cross species transplantation of cells into the gastrointestinal tract. Further, the gene replacement methods proposed in Applicants' arguments have not been accomplished in the art, and moreover removing a single antigen by these methods would not alter the immunogenicity to the complete cell. With respect to specific guidance for implantin cells to the gastrointestinal tract Applciants argue that these are well known. Applicants have not provided any evidnece to this assertion and Examiner is unaware of any teaching in the prior art for successfully implanting stem cells into the gastrointestinal tract, in particular with respect to treating any specific disorder. With respect to the working example, it is unclear if the -/-NOS mouse represents any specific condition or disease. While the animal presents with a particular phenotype, it is not clear if any naturally occuring condition results from a lack of NOS formation. Arguments directed to the rejections made under 35 USC 102 have not been considered because the claim amendments have not been entered. With respect to the traverse of the restriction requirement it is noted that the original claims were linked by the treatment of any disorder (see claim 1) of which some of the possble disorders were specifically set forth in claim 16. The basis of the art rejection which have been set forth is to demonstrate that the generic claim is anticipated and not found allowable, and that other species will not be examined. With respect to the extent of the elected species, the search and examination of the claimed method has focused on the ability to practice the claimed method for treating degenerative disorders, in particular in the gastrointestinal organ as drawn to the elected species.